

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 007184-16	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2004/022817	International filing date (<i>day/month/year</i>) 15 July 2004 (15.07.2004)	Priority date (<i>day/month/year</i>) 23 July 2003 (23.07.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant PR PHARMACEUTICALS, Inc.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 23 January 2006 (23.01.2006)
	Authorized officer Simin Baharlou Telephone No. +41 22 338 71 30

Form PCT/IB/373 (January 2004)

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PATENT COOPERATION TREATY

REC'D 17 OCT 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:
JENNIFER M. MCCALLUM
THE MCCALLUM LAW FIRM, LLC.
132 KOLAR CT
ERIE, CO 80516

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 007184-16		Date of mailing (day/month/year) 14 OCT 2005
International application No. PCT/US04/22817		FOR FURTHER ACTION See paragraph 2 below
International filing date (day/month/year) 15 July 2004 (15.07.2004)	Priority date (day/month/year) 23 July 2003 (23.07.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 9/14, 9/16 and US CL: 424/489, 490, 491, 493, 497, 498		
Applicant PR PHARMACEUTICALS		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Date of completion of this opinion 19 September 2005 (19.09.2005)	Authorized officer S. Tran <i>Janice Ford</i> Telephone No. 571-272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/22817

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/22817

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>7, 9, 16, 19-36</u>	YES
	Claims <u>1-6, 8, 10-15, 17, 18</u>	NO
Inventive step (IS)	Claims <u>7, 9, 16, 19-36</u>	YES
	Claims <u>1-6, 8, 10-15, 17, 18</u>	NO
Industrial applicability (IA)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-6, 8, 10-15, 17 and 18 lack novelty under PCT Article 33(2) as being anticipated by Bodmer et al. US 5,876,761 A. Bodmer discloses a sustained release composition comprising octreotide (active agent) encapsulated in a biodegradable, biocompatible polymer matrix (column 3, lines 26-32). Polymer includes linear and branched polyesters, polylactic acid, polyglycolic acid, polycaprolactone, or polyalkylene glycol (column 6, lines 54-61). Octreotide to be encapsulated can be in the form of complexes with inorganic acid including parnoic acid (column 6, lines 24-53). The process for preparing the microcapsule is disclosed in columns 8-11.